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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Guy Rome

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05/30/2008

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EXAMINER

VU, QUYNH-NHU HOANG

ART UNIT

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/803,512	<b>Applicant(s)</b> ROME, GUY	
	<b>Examiner</b> QUYNH-NHU H. VU	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 30-39 is/are pending in the application.
- 4a) Of the above claim(s) 34 and 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 30-33, 37-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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## DETAILED ACTION

### *Response to Amendment*

Amendment filed on 4/24/08 has been entered.

Claims 30-39 are present for examination.

Claims 1-29 are cancelled.

Applicant's arguments filed on 4/24/08 have been fully considered but are not persuasive.

Therefore, claims 30-39 are rejected in the same ground rejections as set forth in the office action mailed 1/24/08

### *Drawings*

The drawings 7A-C are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the recitation: "**a distal portion of the passageway including a valve having a closed proximal end with a slit and an open distal end, the valve proximal end distal of the engagement feature**" of claim 30; and the recitation "**the engagement features comprise an O-ring, and wherein a wall defining the proximal portion of the passageway proximal of the O-ring is tapered**" of claim 33; the recitation "**the engagement feature comprises a compression ring configured to grip a tip of the tunneler**" of claim 39 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may

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be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Objections***

Claims 30 and 37 are objected to because of the following informalities: the recitation: "a valve having a closed proximal end with a slit and an open distal end, the valve proximal end distal of the engagement feature" of claim 30; and the recitation "a distal portion of a connector housing lumen including a valve having a closed proximal end with a slit and an open distal end" of claim 37 do not disclose in Figs. 7A-C or para [0047-0049] of the Specification. There are no combination elements of "catheter, connector 502, and valve" show in Figs. 7A-C. Appropriate correction is required.

Does Applicant mean that: an engagement feature is as O-ring 100; an instrument is as syringe 40 or tunneler 50?

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 30 is misdescriptive. Applicant recites that "a proximal portion of the passage way including an engagement feature configured to connect an end of an instrument to the connector" does not match with drawings. According to Figs. 7C shows that a connector 502 including a distal end attached to a proximal end of the catheter 50 (this recitation show in Fig. 7C), however, another recitation

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“an engagement feature 500 configured to connect an end of an instrument 40 to the connector 502 (Fig. 7B). In Figs. 7B or 7C, the connector housing 502 is connected either instrument 40 or a catheter 50, but the Figs do not show that combination of the connector housing 502 is connected with a catheter 50 and an instrument 40 in same Figure. Figs. 2-3 do show these limitations as discussed above. However, Figs. 2-3 is non-elected Species.

According to Fig. 7C shows that **a distal portion (not proximal portion)** of the passageway is including an engagement feature 500 or (100 of Figs. 2-3) (adapter assembly; or O-ring) configured to connect an end of an instrument (such as tunneler 50 showed in Fig. 3) to the connector. Only Figs. 2-3 show the limitation above such as: an engagement feature 100 includes an O ring 100 to connect to an end of an instrument 50 to the connector.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 30-31, 33, 37-39 are rejected under 35 U.S.C. 102(e) as being anticipated by anticipated by Canauld et al. (US 2004/0193119).

As best as understood, Canauld discloses that a catheter assembly comprising: a catheter 500 including a lumen 504 (Fig. 9); a connector 200, 270 (Figs. 2-3), 700 (Figs. 19-20) including a distal end attached to a proximal end of the catheter, and a passageway 278 (Fig. 3) in a fluid communication with the at least one lumen; a proximal portion of the passageway including an engagement feature (such as a thread 286) to connected an instrument to the connector (such as connected to port 400 or tunneler 300 or 350); a valve 272 (Fig. 3) or 714 (Fig. 20); O-ring 250 (see para 0039).

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Regarding claims 37-39, Canauld discloses all claimed subject matter as discussed above.

Canauld further discloses that an adaptor (420, can be a syringe adaptor).

Claims 30-33, 37-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Stevens et al. (US 5,935,112).

As best as understood, Stevens discloses, Figs. 1-10, a device comprising: a catheter 250, a connector housing 42 including a distal end attached to a catheter or guide wire (250, Fig. 5), and a passageway in fluid communication with the lumen, a proximal portion of the passage way including an engagement feature to connect an end of an instrument 300 to the connector; a distal portion of the passageway including a valve 36 or 44; an O-ring 48; a syringe adaptor 46.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Canauld or Stevens.

Canauld or Stevens discloses the claimed invention, see rejected above, Canauld further discloses that a guide wire (see para 0004) is very well-known in the art introduced in to the catheter device. Canauld does not disclose the connector comprises a material having a hardness in the range of about 90 Shore A to 90 Shore D, and the valve comprises a material having a hardness in the range of about 40 Shore A to about 60 Shore A. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the material of the connector and valve listed above, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

### ***Response to Arguments***

Applicant's arguments filed 4/24/08 have been fully considered but they are not persuasive.

With respect to rejection 112, Examiner still maintains the rejection. However, Examiner would like to express the issue more clearly. Please see the rejection above.

Applicant argues that Canaud does not state "a valve is having a closed proximal end with a slit and an open distal end" as claimed is described.

In response, Canaud clearly discloses that: a valve 272 is a bi-directional valve or duckbill valve, although those skilled in the art will recognize that other types of valve maybe used" see para [0043].

Therefore, the valve 272 is inherently/must have a slit/small hole for fluid flow. The slit/hole closed at one end at free stage; and the slit opened for fluid flow. Furthermore, the valve 272 can be used with other types of valve. One silk in the art would recognize that the structure of valve having a closed proximal end with a slit and an open distal end is not the new invention in the valve art.

In response to applicant's argument that Stevens does not show "either syringe adaptor including a distal end configured to slide over the tapered proximal end of the connector housing or receive a male luer portion of the syringe", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it will meet the claim. Furthermore, In Figs. 1-10, special in Fig. 2, the syringe adaptor 46 is able to slide in to the connector housing 42 and a proximal opening 222 configured to able receive a male luer portion of the syringe.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH

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shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu  
Examiner  
Art Unit 3763